IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Heath, et al.	Examiner:	Jeffrey S. Lundgren
Serial No.:	09/361,829	Group Art Unit:	1631
Filed:	July 27, 1999	Docket:	101.003US01
Title:	COMPUTER IMPLEMENTED NUCLEIC ACID ISOLATION METHOD AND APPARATUS		

AMENDMENT AND RESPONSE

Commissioner for Patents
Washington, D.C. 20231

In response to the Office Action mailed October 4, 2000, Applicant responds as follows:

REMARKS

Election/Restriction

Restriction was made to Claims 1-19 and Claims 20-22. In a telephone conversation with the Examiner on September 18, 2000, a provisional election was made to prosecute Group I, claims 1-19. Applicant hereby affirms that election and has canceled claims 20-22. Applicant reserves the right to file the remaining claims in a divisional application at a later date.

Rejections Under 35 U.S.C. § 103

Claims 1-7, 9-10 and 14-18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Carlson et al. (U. S. Patent No. 5,773,221) in view of Stephens et al. (U. S. Patent No. 5,856,133), in view of Dionne et al. (U. S. Patent No. 5,800,828) in view of Bacus et al. (U. S. Patent No. 4,175,860).

The Office Action asserts that Bacus teaches a method and an automated laboratory apparatus for performing the method, and how automation is advantageous over high-throughput, human-performed, laboratory methods, and cites for support column 1, lines 31-59 of Bacus. A reading of Bacus indicates that Column 1, lines 31-59 is a detailed analysis of 20 years of failure in such endeavors, not successes. Further, Bacus, at Column 1, lines 39-39, indicates that automation might be advantageous, but goes on to detail how it has not been

advantageous in lines 40-59. Applicant is unaware how a list of automation failures is proper support for automation.

Also, Bacus is directed solely to pap smear analysis, a completely different process than isolation of nucleic acid, as is recited in the present claims. Bacus performs come analysis of cells on a slide. The claimed invention performs no analysis. It performs a method. Bacus would require extensive modification to perform the nucleic acid isolations discussed in the application. Bacus does not contain any inkling that its analysis, which consists primarily of taking pictures at two different resolutions of a stationary sample and analyzing the pictures, is anything other than routine analysis.

Further, the Office Action implies that isolation of proteins and of nucleic acid are processes that can properly be cited together in support of a combination of references. Applicant traverses this implication, and submits that proteins and nucleic acids are distinctly separate. In the isolation of nucleic acid, as the present claims are directed, proteins are a contaminant and are not desirable. To suggest that references directed to isolation of proteins are applicable to the isolation of nucleic acid is not proper.

The various claims 1, 6, 9, and 14 each contain elements not present in the cited art. For example, claim 1 recites "a computer readable medium for controlling the operation of an automated machine" and a method performed on a computer including "issuing a command set to initiate nucleic acid isolation functions." No such disclosure is present in Bacus, the only document cited pertaining to automation. The teachings of Bacus are summarized above, and Applicant can find no mention in Bacus of a computer readable medium used for the purpose of claim 1, nor can Applicant find any mention in Bacus of command sets for isolation of nucleic acid.

Claim 6 recites "a computer system for configuring a machine to automatically perform a method of isolating nucleic acids." The machine includes a computer and a computer readable medium for the output of a command series to control nucleic acid isolation. No such disclosure is taught or suggested in Bacus. No combination of Bacus with any of the other cited art is suggested in any of the cited art.

Claim 9 recites "a control module for controlling the operation of an automated nucleic acid isolation apparatus" and includes a processor and a program module, the program module "issuing commands to the automated nucleic acid isolation apparatus." Claim 14 recites "a computer control module for an automated nucleic acids isolation apparatus" including "a plurality of sub-modules ... comprising machine readable instructions for creating a command ... to perform a process step of the nucleic acids isolation process." Neither Bacus nor any combination of Bacus and any of the other cited art teaches or suggests that they can be combined. The elements of the claims are not present, and no combination of the cited art rises to the level of such a suggestion of any combination. There is no motivation to combine the references. Bacus is directed toward pap smear analysis, and is not art relevant to the problems of nucleic acid isolation. Further, even if Bacus were relevant, it outlines 20 years of automation failures, not successes. The relied upon disclosure in Bacus is non-enabling as to automation that even works, much less disclosure relevant to nucleic acid isolation.

None of the documents cited in the Office Action, either alone or in combination, are suitable to support a prima facie case of obviousness, which requires that all of the elements be present in the combination of the references.

Applicant respectfully submits that claims 1-7, 9-10, and 14-18 are allowable.

Claim 8 was rejected under 35 U. S. C. § 103(a) as being unpatentable over Carlson et al., in view of Stephens et al., in view of Dionne, et al., in view of Bacus et al., and further in view of Thrush (U. S. Patent No. 5,692,144). Claim 8 depends from and further defines patentably distinct claim 6, and is also believed allowable. Thrush simply shows a graphical user interface and does not add any usable discussion of teachings or suggestion that would allow the original combination. As such, the rejection fails to state a prima facie case of obviousness with respect to claim 8. Applicant respectfully submits that claim 8 is allowable.

Claims 11 and 19 were rejected under 35 U. S. C. § 103(a) as being unpatentable over Carlson et al., in view of Stephens et al., in view of Dionne et al., in view of Bacus et al., and further in view of Johnson et al. (U. S. Patent No. 5,584,039). Claims 11 and 19 depend from and further define patentably distinct claims 9 and 14, respectively, and are also believed

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allowable. Johnson once again adds nothing to the analysis allowing the original combination. Applicant respectfully submits that claims 11 and 19 are allowable.

Claim 12 was rejected under 35 U. S. C. § 103(a) as being unpatentable over Carlson et al., in view of Stephens et al., in view of Dionne et al., in view of Bacus et al., and further in view of Poulter et al. (U. S. Patent No. 5,802,389). Claim 12 depends from and further defines patentably distinct claim 9, and is believed allowable. Similar to the discussion of claims 8, 11, and 19, Poulter does not add to the analysis of the original rejection. Applicant respectfully submits that claim 12 is allowable.

Claim 13 was rejected under 35 U. S. C. § 103(a) as being unpatentable over Carlson et al., in view of Stephens et al., in view of Dionne et al., in view of Bacus et al., and further in view of McNutt (U. S. Patent No. 5,802,389). Claim 13 depends from and further defines patentably distinct claim 9, and is believed allowable. As in the use of other references additional to the rejection of the independent claims used in the rejections of claims 8, 12, 11, and 19, McNutt does not add to the analysis of the original rejection. Applicant respectfully submits that claim 13 is allowable.

CONCLUSION

Claims 20-22 have been canceled without prejudice, and applicant reserves the right to file a divisional application thereupon. Claims 1-19 remain pending in the application.

Applicant believes that the claims are in condition for allowance and respectfully requests a Notice of Allowance be issued in this case. If the Examiner has any questions regarding this application, please contact the undersigned attorney at (612) 252-0014.

Respectfully submitted,

Date: 4 Jan 2001

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